

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING)	
PHARMACY, INC.)	
PRODUCTS LIABILITY LITIGATION)	MDL No. 2419
)	Dkt. No 1:13-md-2419 (RWZ)
)	
)	
This Document Relates to:)	
)	
Suits Naming the SSC Defendants)	
)	

**SSC DEFENDANTS' SUR-REPLY TO THE PSC'S MOTION TO EXTEND TIME TO
FILE CERTIFICATES OF GOOD FAITH [DOC. 3121]**

Specialty Surgery Center, Crossville, PLLC ("SSC"), Kenneth R. Lister, MD ("Dr. Lister"), and Kenneth Lister, MD, PC ("Dr. Lister's Practice") (collectively the "SSC Defendants") file this sur-reply further explaining why Tennessee law does not allow this Court to just ignore the fact that multiple Plaintiffs did not file a certificate of good faith with their health care liability claims as required by Tennessee law¹.

The PSC's *Motion to Extend Time to File Certificates of Good Faith* [Doc. 3121] must be denied and the SSC Defendants' *Motion to Dismiss* [Doc. 3086] must be granted.

¹ Tenn. Code Ann. § 29-26-122.

1. Procedural posture

There are two pending motions on this issue: (1) the SSC Defendants' Motion to Dismiss 15 suits² for failing to file the certificate of good faith required by the Tennessee Health Care Liability Act ("THCLA"); and (2) the PSC's motion for permission to allow late-filed certificates.³ This sur-reply rounds out the briefing on these two motions. It also identifies two important Tennessee appellate opinions issued after briefing began.

2. Introduction

With respect to the Branstetter Actions, the PSC argues that they were in a "catch 22" because of a conflict between the THCLA statute of limitations and the TPLA statute of limitations.^{4 5} The SSC Defendants already demonstrated the flaws with this position in prior briefing.⁶ This sur-reply will not repeat those points. Instead, it will focus on the Remaining Actions and the Cain Actions.

The PSC concedes the Remaining Actions and Cain Actions did not comply with Tenn. Code Ann. § 29-26-122 when bringing health care liability claims for negligence and failure to warn/informed consent. The PSC offers no real reason for the failure; it just asks for forgiveness. However, once the Court examines the procedural history and governing law, it will be clear that the PSC's motion for extension must be denied and that the SSC Defendants' motion to dismiss must be allowed.

² The cases are broken down into three categories: the Remaining Actions, the Cain Actions, and the Branstetter Actions. These categories of cases are defined repeatedly in the extensive briefing on these issues and will not be repeated here. See, e.g., Doc. 3137 at 2.

³ Docs. 3086, 3121.

⁴ The Branstetter Plaintiffs could not seriously argue that they did not know that the THCLA applied when they (1) sent presuit notice before filing their original complaint, (2) disclaimed application of the THCLA in their original complaint, and (3) later amended their complaints to add THCLA claims.

⁵ See Doc. 3122 at 4-5.

⁶ Doc 3137 at 21-23.

3. Stovall supports dismissal of these cases.

In the latest papers, the PSC tries to bail out the Remaining Actions and Cain Actions by citing *Stovall v. UHS Lakeside, LLC*⁷ and nebulous, unattested-to “confusion” about the applicable law. The PSC’s reply (incorrectly) cites *Stovall* extensively for two propositions: (1) good cause is the appropriate standard for evaluating whether to grant an extension to file a certificate of good faith, and (2) confusion as to the law is automatically good cause.⁸ However, when one actually reads *Stovall*, it is clear that neither is correct, and *Stovall* actually supports dismissal of these cases.⁹

a. First and foremost, extraordinary cause (not good cause) is the appropriate standard to apply in the Remaining Actions and Cain Actions.

In *Stovall*, the Court of Appeals drew a clear distinction between two categories of cases:

1. Cases where a plaintiff timely filed a certificate – albeit a deficient one – with the complaint making health care liability claims (which is what the plaintiff did in *Stovall*)

versus

2. Cases where a plaintiff filed no certificate at all with the complaint alleging health care liability (the situation here).

The PSC ignores this distinction and misleadingly lumps all the cases into the first group. But, they actually belong in the second group. The Plaintiffs in the Cain and Remaining Actions did not file *any* certificate when they brought health care liability

⁷ No. W2013-01504-COA-R9-CV, 2014 WL 2155345, at *1 (Tenn. Ct. App. April 22, 2014) (overruled on other grounds).

⁸ Doc. 3168 at 3-4.

⁹ The PSC confusingly states that the SSC Defendants did not address *Stovall* in their briefing. This is just not true. See Doc. 3137 at 7, n. 17.

claims in their amended complaints. If the Court follows *Stovall*, this distinction impacts the analysis.

Stovall analyzed the first scenario: whether a plaintiff who timely filed a deficient certificate established good cause for an extension to fix the deficiency. Since that is not the case in the Remaining Actions or the Cain Actions, the Court must look at what *Stovall* says to do in the second scenario: where a plaintiff fails to timely file any certificate with the complaint alleging health care liability. In that scenario, *Stovall* says that *extraordinary cause* is the appropriate standard:

[I]t appears that when a plaintiff has failed to file any certificate of good faith with the complaint, the only avenues of relief from the mandate of dismissal are based on ‘the failure of the provider to timely provide copies of the claimant’s records’ or extraordinary cause. However, when the issue is the filing of a certificate ‘in compliance with this section,’ the plaintiff has an additional avenue of relief: showing good cause. Thus, a plaintiff who has filed a certificate of good faith that is not fully compliant with Tennessee Code Annotated Section 29–26–122 may seek an extension to file a certificate fully compliant with the statutory requirements.¹⁰

The PSC’s interpretation of the statute, that good cause applies to all requests to late-file a certificate, would render superfluous the language in § 29-26-122(a) regarding extraordinary cause.¹¹ The only way to give effect to both the extraordinary cause language in § -122(a) and the good cause language in § -122(c) is to follow what the Court of Appeals said in *Stovall*: When a certificate is filed without the proper content, a plaintiff can show good cause to fix it. But, when a plaintiff filed *no* certificate with the complaint, they must demonstrate extraordinary cause to excuse it.¹²

¹⁰ *Stovall*, 2014 WL 2155345, at *11.

¹¹ Even under the PSC’s interpretation, the extraordinary cause standard would apply to the Remaining Actions where no certificate was ever filed.

¹² *Lanier v. Rains*, 229 S.W.3d 656, 661 (Tenn. 2007) (“We presume that every word in a statute has meaning and purpose; each word should be given full effect if the obvious intention of the General Assembly is not violated by so doing.”) (internal citations omitted).

Here, the Plaintiffs in the Cain and Remaining Actions did not file certificates of good faith with the first complaints they filed alleging health care liability (*i.e.*, negligence and informed consent claims in their first amended complaints).¹³ That is undisputed. This material difference from *Stovall* requires application of the extraordinary cause standard.

Of note, the PSC does not even attempt to argue that the claimed confusion here satisfies the extraordinary cause standard. Thus, if the Court follows *Stovall* and finds that extraordinary cause is the correct standard, the Court need proceed no further. The PSC apparently concedes that extraordinary cause does not exist to excuse compliance in the Remaining Actions and Cain Actions.

b. The Plaintiffs' purported confusion about the statute is nothing like the confusion at issue in *Stovall* and does not even satisfy the good cause standard.

Even if the Court applies a good cause standard, the Plaintiffs still do not prevail. The PSC basically just shrugs its shoulders and says conclusively that the Plaintiffs' counsel did not know what law they were proceeding under.¹⁴ This confusion comes nowhere close to the ambiguity at issue in *Stovall*, upon which the PSC relies. It is flat absurd to say that these Plaintiffs were "confused" about whether their informed consent claims were health care liability claims (to say nothing of their negligence claims).

The plaintiff in *Stovall* had a legitimate question about an ambiguity in the law. At issue in *Stovall* was the requirement that the certificate state the number of times the

¹³ The PSC misleadingly states that "The Cain Actions filed original claims and later amended that complaint and filed a Certificate of Good Faith with the amended complaint." Doc. 3168 at 1. While this is technically true, it fails to acknowledge that the certificate was first filed with the second amended complaint in the Cain Actions. Prior to that, the Plaintiffs in the Cain Actions filed first amended complaints alleging negligence and informed consent without a certificate.

¹⁴ Doc. 3168 at 4-5.

plaintiff's lawyer violated the certificate of good faith requirement.¹⁵ The plaintiff's lawyer timely filed a certificate with the original complaint, but did not affirmatively state, *I have been found in violation of the statute zero times*.¹⁶ The plaintiff's lawyer later filed an affidavit with her motion for an extension explaining she was confused about whether she needed to actually state the number of prior violations if the number was zero.^{17 18} The Court of Appeals found that the trial court did not abuse its discretion in finding that this confusion constituted good cause.¹⁹

The alleged confusion here is nothing like *Stovall*.²⁰ The PSC claims the lawyers in the Remaining Actions and in the Cain Actions were confused about whether they were proceeding under the THCLA, the TPLA, or both.²¹ While these Plaintiffs may have been confused about whether the THCLA applied when they filed original complaints alleging only product liability claims, there could be no "reasonable confusion" about whether the THCLA applied to the negligence and informed consent claims they included in their amended complaints without a certificate. At minimum, lack of informed consent claims have *always* been malpractice/health care liability claims in Tennessee,²² as this Court recognized in 2014.^{23 24} The PSC does not even attempt to

¹⁵ *Id.* at *14-15.

¹⁶ *Id.*

¹⁷ *Id.* at *14-16.

¹⁸ The Tennessee Supreme Court has since issued an opinion answering this question in the negative, holding that plaintiff's counsel need not disclose the number of prior violations if the number is zero and reversing *Stovall* on this narrow issue. *Davis v. Ibach*, 465 S.W.3d 570, 574 (Tenn. 2015).

¹⁹ *Stovall*, 2014 WL 2155345, at *18 (recognizing a split of authority over whether reasonable confusion as to the law constitutes good cause).

²⁰ As a practical matter, there is no affidavit in the record to support the claim of confusion upon which the Court can base a finding of good cause. *Stovall* and *Brandon* seem to suggest this is almost a prerequisite to such a finding.

²¹ Doc. 3168 at 4-5.

²² See Tenn. Code Ann. § 29-26-118 (informed consent statute, part of medical malpractice – now health care liability – section; first passed in 1975); see, e.g., *Cardwell v. Bechtol*, 724 S.W.2d 739, 749 (Tenn. 1987) (analyzing informed consent case under malpractice statute); *Ashe v. Radiation Oncology Assocs.*, 9 S.W.3d 119, 120 (Tenn. 1999) (analyzing causation in a "medical malpractice informed consent" case).

explain what confusion about the THCLA has to do with these separate claims for negligence and informed consent.

Even more damning, prior to filing suit, the Plaintiffs in the Remaining Actions and Cain Actions (the Plaintiffs who claim they were confused about whether the THCLA applied) sent SSC notice that they were going to file *health care liability claims*.²⁵ These Plaintiffs could not be confused about whether the THCLA applied when they affirmatively stated presuit that they intended to sue under the THCLA.²⁶

The PSC wholly fails to address these contradictions between its version of events and reality, instead lumping together all three categories of cases in the hopes the Court will do the same. Once the Court examines each category of cases separately, it will see that the PSC's claim of confusion does not hold up for the Remaining Actions and the Cain Actions. These cases do not even satisfy the good cause standard. Accordingly, the motion for extension should be denied.

²³ Doc. 1360, at 35 ("As for the lack of informed consent claims, plaintiffs allege that the Tennessee Clinic Defendants failed to warn them that they were being administered 'an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer' and failed to inform them of 'the risks and benefits of the procedure[] before it was performed.'...The Tennessee Clinic Defendants correctly point out that lack of informed consent claims are governed by the THCLA").

²⁴ The PSC's reply states that *Stovall* is the only case to address application of the good cause standard. Doc. 3168 at 2. This is just wrong. The SSC Defendants identified numerous other cases in prior briefing. Additionally, the *Stovall* court discussed one such case in detail in its opinion, *Brandon v. Williamson Medical Center*, 343 S.W. 3d 784 (Tenn. Ct. App. 2010).

²⁵ Presuit notices for nine of the ten Cain and Remaining Actions are attached as Exhibit 1. SSC has no record of receiving presuit notice in the tenth case (*Hubbard*), but the amended complaint in that case affirmatively alleges the Plaintiff sent presuit notice to SSC on September 10, 2013 (weeks before filing the original complaint). See *Hubbard*, Dkt. No. 1:13-cv-12922, Doc. 13 at ¶ 10.

²⁶ The Court of Appeals rejected a similar "suspect" excuse in *Brandon v. Williamson Medical Center*, 343 S.W. 3d 784 (Tenn. Ct. App. 2010), discussed at length in *Stovall* but ignored by the PSC. In *Brandon*, the plaintiff claimed she did not know a certificate of good faith needed to be filed. *Id.* at 789. The Court of Appeals determined this claim to be "suspect" given that she sent presuit notice under the THCLA prior to filing suit. *Id.* at 789-90.

4. Two opinions recently issued by the Tennessee Court of Appeals further support dismissal of these cases.

Finally, the Tennessee Court of Appeals issued two opinions since the Defendants' last filing which are relevant to both the motion to dismiss and the PSC's motion for an extension.

*Redick v. Saint Thomas Midtown Hosp.*²⁷

In *Redick v. Saint Thomas Midtown Hosp.*, the plaintiff filed a health care liability action without a certificate of good faith.²⁸ Because evaluating the appropriateness of the medical care at issue fell within the common knowledge of laymen, the court found that Tennessee's "common knowledge" exception applied, and no expert testimony was required to prove a breach of the standard of care.²⁹ The plaintiff apparently assumed this also exempted her from the certificate requirement. However, the Tennessee Court of Appeals held that the plaintiff still needed a certificate because she needed expert testimony to prove medical causation.³⁰ The Court of Appeals affirmed dismissal of the suit because the plaintiff did not file a certificate of good faith to address the causation element.³¹

Here, the Plaintiffs argue they did not need to file a certificate of good faith because they did not need expert testimony to prove a breach of the standard of care for their strict product liability claims.³² But, the fact that they might not have needed expert testimony on the breach element does not end the analysis. *Redick* establishes

²⁷ *Redick v. Saint Thomas Midtown Hosp.*, No. M2016-00428-COA-R3-CV, 2016 WL 6299465 (Tenn. Ct. App. Oct. 26, 2016).

²⁸ *Id.* at *3-4.

²⁹ *Id.* at *4.

³⁰ *Id.* at *5.

³¹ *Id.*

³² Doc. 3122 at 6-9.

that the Plaintiffs still needed to file certificates of good faith because they need expert testimony to prove medical causation.³³

*Carter v. Methodist Healthcare Memphis Hosps.*³⁴

In *Carter v. Methodist Healthcare Memphis Hosps.*, the plaintiff failed to comply with the presuit notice requirements of Tenn. Code Ann. § 29-26-121.³⁵ The Court of Appeals addressed two issues relevant to the SSC Defendants' Motion to Dismiss: (1) the "extraordinary cause" standard under the Health Care Liability Act and (2) the interaction between the § -121 and Tenn. R. Civ. P. 15 (which mirrors FRCP 15).³⁶

Affirming dismissal, the Court of Appeals found that a plaintiff's "claimed ignorance as to what was necessary to comply with the [Health Care Liability Act]...does not justify a finding of extraordinary cause."³⁷ This forecloses any contention that Plaintiffs' counsel's misunderstanding of the certificate of good faith requirement constitutes extraordinary cause.

The Court of Appeals also determined that "[Tenn. R. Civ. P.] 15 simply does not apply" because presuit notice is not a pleading.³⁸ Here, as in *Carter*, there is no conflict between Fed. R. Civ. P. 15 and the Health Care Liability Act (as the PSC claims) because the rule does not apply. A certificate of good faith is also not a pleading subject to the rule.

³³ As explained in the SSC Defendants' prior briefing, *Ellithorpe* rejected the PSC's contention that expert testimony is not required to establish a breach of the standard of care here. Doc. 3137 at 19-21. Even assuming the PSC is correct, *Redick* holds that a certificate of good faith is required on the causation element.

³⁴ *Carter v. Methodist Healthcare Memphis Hosps.*, No. W2016-00024-COA-R3-CV, 2016 WL 6493229 (Tenn. Ct. App. Nov. 2, 2016).

³⁵ *Id.* at *1.

³⁶ *Id.* at *4.

³⁷ *Id.* at *11.

³⁸ *Id.* at *13.

5. Conclusion

The PSC continues to conflate the issues and governing law in a final attempt to save these 15 cases from dismissal. In short, there is nothing in the record upon which the Court can base a finding of either extraordinary cause or good cause to excuse non-compliance. The Plaintiffs have had ample opportunity to submit an affidavit or other proof for the Court's consideration but have not done so.

Even if the Court accepts as true the unsupported assertions in the PSC's briefing, the "confusion" cited by the PSC as the basis for the extension does not satisfy the good cause, let alone extraordinary cause, standard, and cannot save these cases from dismissal. The Plaintiffs filed negligence and informed consent claims without certificates. They have not demonstrated extraordinary or good cause for failing to comply. It is as simple as that.

These 15 cases failed to comply with the certificate of good faith requirement. The Court should decline the PSC's invitation to, years later, simply say, "No big deal," and allow them to go forward with no consequence. That would ignore the will of Tennessee's legislature, the plain language of the statute, and the applicable case law. The PSC's motion for extension should be denied, and the SSC Defendants' motion to dismiss should be allowed.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

C.J. Gideon, Jr.*

Chris J. Tardio*

Alan S. Bean**

Matthew H. Cline*

315 Deaderick Street, Suite 1100

Nashville, TN 37238

Ph: (615) 254-0400

Fax: (515) 254-0459

chris@gideoncooper.com

AND

**BREWER, KRAUSE, BROOKS & CHASTAIN,
PLLC**

/s/ Parks T. Chastain

PARKS T. CHASTAIN**

KENT E. KRAUSE**

ASHLEY E. GENO**

P. O. Box 23890

Nashville, TN 37202-3890

(615) 256-8787 (PTC)

(615) 256-8985 (fax)

pchastain@bkblaw.com

kkrause@bkblaw.com

ageno@bkblaw.com

Attorneys for the SSC Defendants

* Admitted pursuant to MDL Order No. 1.

** Admitted *pro hac vice*.

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/s/ Chris J. Tardio

Chris. J. Tardio